commodities to the table in paragraph (a)(2).

ii. The text of paragraph (b) is removed and reserved.

§ 180.479 Halosulfuron-methyl; tolerances for residues.

(a) *General.* * * *

(2) * * *

Commodity	Parts per million
* * * * *	
Asparagus	0.8
Bean, dry, seed	0.05
Bean, snap, succulent	0.05
* * * * *	
Vegetables, fruiting (except cucurbits), group	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

* * * * *

[FR Doc. 02–23995 Filed 9–19–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0219; FRL–7198–5]

Methoxyfenozide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of methoxyfenozide and the combined residues of methoxyfenozide and its glucuronide metabolite on various agricultural food commodities. This regulation also establishes tolerances for indirect or inadvertent residues for methoxyfenozide and establishes tolerances for indirect or inadvertent combined residues for methoxyfenozide and its metabolites on various food commodities, and increases the already established tolerances for residues of methoxyfenozide and increases the already established tolerances for the combined residues of methoxyfenozide and its glucuronide metabolite on various food commodities. Rohm and Haas Company and the Interregional Research Project Number 4 (IR–4), Technology Center of New Jersey, the State University of New Jersey requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The chemical was subsequently purchased by Dow Agrosciences from Rohm and Haas Company. The specific food commodities affected by the establishment or increase of these tolerances are set forth in the preamble to this document.

DATES: This regulation is effective September 20, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0219, must be received on or before November 19, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0219 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph M. Tavano, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–6411; e-mail address: *tavano.joseph@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet home page at http://www.epa.gov/. To access this document, on the home page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00 .html*, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0219. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Registers** of January 10, 2000, 65 FR 1370–1381; FRL–6394–6; March 19, 2001, 66 FR 15432–15459; FRL–6766–7; May 23, 2001, 66 FR 28482–28487; FRL–6782–5 and August 24, 2001, 66 FR 44629–44634; FRL–6796–2; and August 14, 2002, 67 FR 52996–53001; FRL–7191–9. EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of a pesticide petitions (PP 9F6033; 9F6062; 0F6201; 0F6213; 1F 6259; 1F6287; 2E6382 and

2E6408) by Rohm and Haas Company,100 Independence Mall West, Philadelphia, PA 19106–2399 and the Interregional Research Project Number 4 (IR–4), Technology Centre of New Jersey, the State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. These notices included a summary of the petitions prepared by Rohm and Haas Company, the registrant or the Interregional Research Project Number 4 (IR–4). There were no comments received in response to these notices of filing.

The petitions requested that 40 CFR 180.544 be amended by establishing tolerances for residues of the insecticide methoxyfenozide in or on almond, hulls; artichoke, globe; field corn grain; field corn forage; field corn stover (fodder); corn, oil; aspirated grain fractions; sweet corn (K + CWHR); sweet corn forage; sweet corn stover (fodder); corn silage; stone fruits crop group; prunes; grapes; Spanish lime; longan; lychee; tree nut crop group; pulasan; raisins; rambutan; fruiting vegetables (except cucurbits); crop subgroup 4A leafy green vegetables; 4B leaf petioles; head and stem Brassica; crop subgroup 5B leafy Brassica greens; at 45.0, 3.0, 0.05, 15.0, 105, 0.2, 1.0, 0.05, 30, 60, 5.0, 5.0, 7.0, 1.0, 2.0, 2.0, 2.0, 0.1, 2.0, 1.5, 2.0, 2.0, 25.0, 10.0, 6.5, 20 parts per million (ppm) respectively and an increase in the established tolerance for residues of methoxyfenozide to 0.1 ppm in milk and an increase in the established tolerances for residues of methoxyfenozide and its glucuronide metabolite in the fat of cattle, goats, horses, hogs and sheep; liver of cattle, goats, horses, hogs and sheep; and meat byproducts (except liver) of cattle, goats, horses hogs and sheep to 0.5, 0.4 and 0.1 ppm respectively. These petitions also requested that 40 CFR 180.544 be amended by establishing time limited tolerances for the indirect or inadvertent residues of methoxyfenozide and its metabolites RH–117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid *N*-tert-butyl-*N*'-(3-hydroxy-2-methylbenzoyl) hydrazide, RH–151,055 glucose conjugateof RH–117,236; 3,5-dimethylbenzoicacid *N*-tert-butyl-*N*-[3(β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide and RH–152,072 the malonylglycosyl conjugate of RH 117,236 in or on root and tuber vegetables; leaves of root and tuber vegetables; bulb vegetables; leafy vegetables (except Brassica); Brassica vegetables; legume vegetables; foliage of legume vegetables; forage, fodder, hay, and straw of cereal grains; grass forage, fodder and hay; forage, fodder, straw and hay of non-grass animal feeds; and herbs and spices when present therein as a result of application of methoxyfenozide to growing crops at 0.05, 0.1, 0.1, 0.2, 0.2, 0.05, 8.0, 7.0, 7.0, 8.0 and 8.0 ppm respectively.

Based on the residue data submitted, EPA has determined that the following changes to the requested tolerances listed above are necessary. A higher tolerance of 125 ppm is required for field corn stover. A higher tolerance of 30.0 ppm is required for vegetable, leafy (except Brassica), leafy greens subgroup. A higher tolerance of 25 ppm is required for vegetable, leafy (except Brassica), leaf petioles subgroup. A higher tolerance of 7.0 ppm is required for vegetables, leafy, Brassica (cole), head and stem subgroup. A higher tolerance of 30.0 ppm is required for vegetables, leafy, Brassica (cole), greens subgroup. A separate tolerance of 0.30 is needed for plums (fresh prune). A lower tolerance of 25.0 ppm is required for almond hulls. A higher tolerance of 2.0 ppm is required for aspirated grain fractions. No tolerance is required for corn silage since residues in silage are covered by the proposed tolerance for field corn forage. A tolerance for processed prunes is not needed. A lower tolerance of 3.0 ppm is required for stone fruit (except plum, fresh prune). The proposed higher tolerances for hog commodities are not needed. A tolerance of 0.02 ppm is required for poultry, fat and 0.02 for poultry, meat. A tolerance of 0.02 ppm is required for eggs. A tolerance of 0.10 ppm is required for poultry, liver and 0.02 ppm for poultry meat byproducts (mbyp) (except liver). Higher tolerances for the indirect or inadvertent residues of methoxyfenozide in or on vegetable, bulb, group; vegetable, root and tuber, group and vegetable, root and tuber, leaves, group at 0.20, 0.10, and 0.20 ppm respectively are required. Tolerances for the indirect or inadvertent residues of methoxyfenozide in or on leafy and Brassica vegetables are not needed since direct tolerances are being established for them. Higher tolerances for the indirect or inadvertent combined residues of methoxyfenozide benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide and its metabolites RH–117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid *N*-tert-butyl-*N*'-(3-hydroxy-2-methylbenzoyl) hydrazide], RH–151,055 [glucose conjugate of RH–117,236; 3,5-dimethyl benzoic acid *N*-tert-butyl-*N*-[3 (β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide and RH–152,072 the malonylglycosyl conjugate of RH 117,236 in or on animal feed, non-grass (forage, fodder, straw, hay), group; grain, cereal, forage, fodder, and straw, group; grass, forage, fodder, and hay, group; herbs and spices, group; vegetable, legume, group; and vegetable, legume, foliage, group at 10.0 ppm, 10.0 ppm, 10.0 ppm, 10.0 ppm, 0.10 ppm and 10.0 ppm respectively are needed.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of the insecticide methoxyfenozide in or on almond, hulls; artichoke, globe; cattle, fat; corn, field, grain; corn, field, forage; corn, field, stover; corn, oil; corn, aspirated grain fractions; corn, sweet (K + CWHR); corn, sweet, forage; corn, sweet, stover; fruit, stone, group (except plum, fresh prune); goat, fat; grape; horse, fat; lime, Spanish; longan; lychee; milk; nut, tree, group; pistachio; plum (fresh prune); poultry, fat; poultry, meat; pulasan; raisin; rambutan; sheep, fat; vegetable,

fruiting (except cucurbits), group; vegetable, leafy (except Brassica), leafy greens subgroup; vegetable, leafy (except Brassica), leaf petioles subgroup; vegetable, leafy, Brassica (cole), head and stem subgroup; vegetable, leafy, Brassica (cole), greens subgroup at 25.0, 3.0, 0.50, 0.05, 15.0, 125.0, 0.20, 2.0, 0.05, 30.0, 60.0, 3.0, 0.50, 1.0, 0.50, 2.0, 2.0, 2.0, 0.10, 0.10, 0.10, 0.30, 0.02, 0.02, 2.0, 1.5, 2.0, 0.5, 2.0, 30.0, 25.0, 7.0 and 30.0 ppm respectively, and for the combined residues of methoxyfenozide and its glucuronide metabolite in or on cattle, liver; cattle, meat byproducts (except liver); eggs; goat, liver; goat meat byproducts (except liver); horse, liver; horse, meat byproducts (except liver); poultry, liver; poultry, meat byproducts (except liver); sheep, liver; and sheep, meat byproducts (except liver) at 0.40, 0.10, 0.02, 0.40, 0.10, 0.40, 0.10, 0.10, 0.02, 0.40 and 0.10 ppm, respectively. EPA also has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for the indirect or inadvertent residues for methoxyfenozide in or on vegetable, bulb, group; vegetable, root and tuber, group; and vegetable, root and tuber, leaves, group when present therein as a result of the application of methoxyfenozide to growing crops at 0.20, 0.10 and 0.20 ppm, respectively and time-limited indirect or inadvertent combined residues for methoxyfenozide and its metabolites RH–117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid *N*-tert-butyl-*N*'-(3-hydroxy-2-methylbenzoyl) hydrazide], RH–151,055 glucose conjugate of RH–117,236; 3,5-dimethylbenzoicacid *N*-tert-butyl-*N*-[3(β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide and RH–152,072 the malonylglycosyl conjugate of RH–117,236 in or on animal feed, non-grass (forage, fodder, straw, hay), group; grain, cereal, forage, fodder, and straw, group; grass, forage, fodder, and hay, group; herbs and spices, group; vegetable, legume, group; and vegetable, legume, foliage, group when present therein as a result of the application of methoxyfenozide to growing crops at 10.0, 10.0, 10.0, 10.0, 0.10 and 10.0 ppm, respectively. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by methoxyfenozide are discussed below as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

In an acute neurotoxicity study in rats (MRID 44617802), statistically significant decreased hindlimb grip strength was observed in male rats at 3 hours (approximate time of peak effect) following a single oral dose of 2,000 milligrams/kilogram (mg/kg) (limit dose) of methoxyfenozide. Decreased hindlimb grip strength was also observed in the male rats at 7 and 14 days, but was not statistically significant. No other systemic or neurotoxic effects were observed in the male rats or in the female rats at any time in this study. Since this marginal effect occurred only in one sex, was statistically significant at only one time, was observed only at the high dose (limit dose) and no other signs of toxicity were observed in the rats in this study, this possible effect is not considered to be biologically significant. In addition, neither decreased hindlimb grip strength nor any other signs of neurotoxicity were observed in any of the animals at any time in a 90–day subchronic neurotoxicity study in rats (MRID 44617803).

In a 2–week range-finding dietary study in rats (MRID 44617722), treatment-related effects were observed at ≥5,000 ppm in the liver (increased liver weights and hepatocellular hypertrophy in males and females), in the thyroid gland (hypertrophy/hyperplasia of follicular cells in males and females), and in the adrenal gland (increased adrenal weights and/or hypertrophy of the zona fasciculata in females). Hypertrophy/hyperplasia of thyroid follicular cells was also observed in males and females at 1,000 ppm, the LOAEL in this study. The NOAEL was 250 ppm. Treatment-related hematological changes were not observed in the rats in this study.

In a 3–month feeding study in rats (MRID 44617722), the predominant treatment-related effects were increased liver weights in males and females and periportal hepatocellular hypertrophy in all males and females at 20,000 ppm (highest dose tested) and at 5,000 ppm. In addition, at 20,000 ppm, a slightly decreased (7–8%) red blood cell (RBC) count and slightly decreased (7–8%) hemoglobin concentration, compared to control rats, were observed in the females. The LOAEL in this study was 5,000 ppm (353 mg/kg/day in males and 379 mg/kg/day in females). The NOAEL was 1,000 ppm (69 mg/kg/day in males and 72 mg/kg/day in females). Although observed in the 2–week dietary study and in the 2–year chronic feeding/carcinogenicity study in rats, treatment-related effects in the thyroid and adrenal glands were not observed in the rats in this 3–month study. There is no available biological explanation for this difference in findings in the studies.

In a 2–year combined chronic feeding/carcinogenicity study in rats (MRID 44617731), the following treatment-related effects were observed at 20,000 ppm (highest dose tested): decreased survival in males, decreased body weight and food efficiency in females during the last year of the study, hematological changes (decreased RBC counts, hemoglobin concentrations, and/or hematocrits; methemoglobinemia; and increased platelet counts) in males and females, increased liver weights and periportal hepatocellular hypertrophy in males and females, thyroid follicular cell hypertrophy in males, altered thyroid colloid in males and females, and increased adrenal weights in males and females. At 8,000 ppm, the following treatment-related effects were observed: hematological changes (decreased RBC counts, hemoglobin concentrations, and/or hematocrits in males and females), liver toxicity (increased liver weights in males and periportal hepatocellular hypertrophy in males and females), histopathological changes in the thyroid (increased follicular cell hypertrophy in males and altered colloid in males) and possible adrenal toxicity (increased adrenal weights in males and females). The LOAEL in this study was 8,000 ppm (411 mg/kg/day in males and 491 mg/kg/day in females), based on the effects described above. The NOAEL was 200 ppm (10.2 mg/kg/day in males and 11.9 mg/kg/day in females). This NOAEL was used to establish the RfD for methoxyfenozide. Utilizing an uncertainty factor (UF) of 100 to account for both interspecies extrapolation (10X) and intraspecies variability (10X), the chronic RfD for methoxyfenozide was calculated to be 0.10 mg/kg/day. No evidence of carcinogenicity was observed in this study. Dosing was considered adequate because of the decreased survival in males and the decreased body weights and food efficiency in females at 20,000 ppm. In addition, the highest dose tested for both males and females, 20,000 ppm (1,045 mg/kg/day males and 1,248 mg/kg/day in females), is higher than the limit dose of 1,000 mg/kg/day.

In a 2–week range-finding study in dogs (MRID 44617724), treatment-

related hematological changes were observed in both males and females at 3,500 ppm, 7,000 ppm, 15,000 ppm and 30,000 ppm (highest dose tested). These changes included decreased RBC counts, decreased hemoglobin concentrations, decreased hematocrits, decreased MCHC, increased MCV, increased MCH, increased Heinz bodies, methemoglobinemia, changes in RBC morphology such as Howell-Jolly bodies and polychromasia, increased reticulocyte counts, increased nucleated RBC and increased platelet counts. At the same dose levels (≥ 3,500 ppm), increased spleen weights and/or enlarged spleens were also observed. At ≥ 7,000 ppm, plasma total bilirubin was increased. The LOAEL in this study was 3,500 ppm (90–184 mg/kg/day in males and females). The NOAEL was 300 ppm (11–16 mg/kg/day in males and females).

In a 3–month feeding study in dogs (MRID 44617724), no treatment-related effects other than a suggestion of decreased body weight gains in males and females were observed in either males or females at the highest dose tested viz. 5,000 ppm (198 mg/kg/day in males and 209 mg/kg/day in females). Although hematological effects were noted in dogs in the 2–week range-finding study at ≥ 3,500 ppm (90–184 mg/kg/day) and in the 1–year chronic feeding study at ≥3,000 ppm (106 mg/kg/day in males and 111 mg/kg/day in females), hematological changes were not observed in this 3–month study at 5,000 ppm (198/209 mg/kg/day). There is no available biological explanation for this difference in findings in the studies.

As part of the 3–month study in dogs (MRID 44617724), some male and female dogs were given 15 ppm (0.6 mg/kg/day) of methoxyfenozide in the diet for 15 weeks followed by an increase in the dietary dose to 15,000 ppm (422 mg/kg/day in males and 460 mg/kg/day in females) for an additional 6 weeks. After about 2 weeks and 6 weeks at 15,000 ppm, hematological examinations were conducted. No hematological changes in these dogs were observed. Apparently, pretreatment of the dogs at 15 ppm for 15 weeks prevented the occurrence of hematological changes which would have been expected to occur based on results in the 2–week and 1–year feeding studies. One possible explanation is that the liver microsomal enzyme system may have been stimulated so much during pretreatment at 15 ppm that the metabolic (detoxification ?) rate of methoxyfenozide was increased to the point where blood levels of methoxyfenozide may have remained below critical effect levels at 15,000 ppm. Another possible explanation is that compensatory mechanisms for replacing damaged RBC in pretreated dogs may have been so efficient that hematological changes were not observed in these dogs even at 15,000 ppm. Other explanations for this finding are also possible.

In a 1–year chronic feeding study in dogs (MRID 44617728), the predominant toxic effects were anemia and signs of an associated compensatory response. At 30,000 ppm, the highest dose tested, the following treatment-related effects were observed in both males and females: decreased RBC counts, decreased hemoglobin concentrations, decreased hematocrits, methemoglobinemia, nucleated RBC, increased platelets, increased serum total bilirubin, bilirubinurea, increased hemosiderin in macrophages in liver and spleen, and increased hyperplasia in bone marrow of rib and sternum. Increased liver weights in males and females and increased thyroid weights in males were also observed at 30,000 ppm. Signs of anemia were also noted at 3,000 ppm and included decreased RBC counts, decreased hemoglobin concentrations, decreased hematocrits, methemoglobinemia, increased platelets, and increased serum total bilirubin and bilirubinurea. The LOAEL in this study was 3,000 ppm (106 mg/kg/day in males and 111 mg/kg/day in females). The NOAEL was 300 ppm (9.8 mg/kg/day in males and 12.6 mg/kg/day in females).

In a 3–month feeding study in mice (MRID 44617723), the only treatment-related effect was decreased body weight gain in males and females at 7,000 ppm, the highest dose tested. The LOAEL in this study was 7,000 ppm (1,149 mg/kg/day in males and 1,742 mg/kg/day in females) and the NOAEL was 2,500 ppm (428 mg/kg/day in males and 589 mg/kg/day in females). In an 18–month carcinogenicity study in mice (MRID 44617729), no treatment-related effects were observed at doses up to and including the limit dose of 7,000 ppm (1,020 mg/kg/day in males and 1,354 mg/kg/day in females). No evidence of carcinogenicity was observed in this study. Dosing was considered adequate because the highest dose tested for both males and females, 7,000 ppm (1,020 mg/kg/day in males and 1,354 mg/kg/day in females, respectively), is higher than the limit dose of 1,000 mg/kg/day.

In a battery of four mutagenicity studies (with and without metabolic activation, as appropriate for the specific study), technical grade methoxyfenozide was negative for genotoxicity in all four studies. The four studies satisfy the new revised mutagenicity guideline requirements for a new chemical (published in 1991). An additional mutagenicity study, performed on RH–117,236 (Metabolite M-B), a metabolite of methoxyfenozide, was also negative for genotoxicity.

Based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies, methoxyfenozide is classified as a ''not likely'' human carcinogen according to the EPA Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996).

In a developmental toxicity study in rats (MRID 44638201), no signs of maternal toxicity in dams or of developmental toxicity in fetuses were observed at the limit dose of 1,000 mg/kg/day. The NOAEL in this study for both maternal toxicity and developmental toxicity was 1,000 mg/kg/day. The LOAEL was >1,000 mg/kg/day. Similarly, in a developmental toxicity study in rabbits (MRID 44617726), no signs of maternal toxicity or of developmental toxicity were observed at the limit dose of 1,000 mg/kg/day. The NOAEL in this study for both maternal toxicity and developmental toxicity was 1,000 mg/kg/day. The LOAEL was >1,000 mg/kg/day.

In neither the developmental toxicity study in rats nor in the developmental toxicity study in rabbits was there any evidence for increased susceptibility of fetuses to *in utero* exposure to methoxyfenozide. In these studies, methoxyfenozide was determined not to be a developmental toxicant.

In a 2-generation (1 litter/generation) reproduction study in rats (MRID 44617727), treatment-related parental toxicity was observed only at 20,000 ppm, the highest dose tested. At this dose, increased liver weights were observed in males and females of both generations and midzonal to periportal hepatocellular hypertrophy was observed in the livers of all males and females of both generations. The LOAEL for parental toxicity was 20,000 ppm (1,552 mg/kg/day for males and 1,821 mg/kg/day for females) and the NOAEL was 2,000 ppm (153 mg/kg/day for males and 181 mg/kg/day for females). There were no treatment-related effects on reproductive parameters for adult (parent) animals. The NOAEL for reproductive toxicity was 20,000 ppm. Since no treatment-related effects were observed in the pups, the NOAEL for neonatal toxicity was also 20,000 ppm. The NOAEL for parental toxicity in this reproduction study is higher than the NOAEL for the 2–year combined

chronic feeding/carcinogenicity study in rats because many of the toxic effects observed in the 2–year study at the LOAEL (hematological changes, liver toxicity, histopathological changes in the thyroid gland and increased adrenal weights) were not examined in the reproduction study.

In a metabolism study in rats (MRID 44617804), ^{14}C-methoxyfenozide was rapidly absorbed, distributed, metabolized and almost completely excreted within 48 hours. The major route of excretion was feces (86–97%) with lesser amounts in the urine (5–13%). An enterohepatic circulation was observed. The test material was metabolized principally by O-demethylation of the A-ring methoxy group and oxidative hydroxylation of the B-ring methyl groups followed by conjugation with glucuronic acid. No significant sex-related or dose-dependent differences in metabolic disposition were noted. Seven metabolites and the parent accounted for 74–90% of the administered dose in all groups. The glucuronide conjugates are considered to be less toxic than the parent compound because glucuronide conjugation is well known to be a commonly occurring ''detoxification'' mechanism in mammalian species since it results in the formation of more polar, more water-soluble metabolites which are readily and easily excreted from the body (in this case, in the bile and urine). Further, based on similarities of chemical structure, the non-conjugated metabolites would be expected to be no more toxic than the parent compound.

In a dermal absorption study in rats (MRID 44638201) using an 80% wettable powder formulation as the test material, the cumulative dermal absorption of test material after a 10 or 24 hour dermal exposure was determined to be 2%.

In a 28–day dermal toxicity study in rats (MRID 44617725), no treatment-related systemic or skin effects were observed at the limit dose of 1,000 mg/kg/day (HDT).

Regarding effects on endocrine organs, methoxyfenozide affected the thyroid gland and adrenal gland in the 2–week and 2–year feeding studies in rats. In the thyroid gland, hypertrophy/hyperplasia of follicular cells and altered colloid were observed in males and females at or near the LOAEL in both of these studies. In the adrenal gland, increased adrenal weights and hypertrophy of the zona fasciculata were also observed in males and females at or near the LOAEL. In addition, in the 1–year chronic feeding study in dogs, increased thyroid weight in males was observed, but only at the very high dose of 30,000 ppm. Other than the morphological changes described above, there were no signs of thyroid or adrenal dysfunction in these or in any other studies on methoxyfenozide.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for methoxyfenozide used for human risk assessment is shown in the following Table 2:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR METHOXYFENOZIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary	None	No appropriate endpoint was identified in the oral toxicity studies including the acute neurotoxicity study in rats and the developmental toxicity studies in rats and rabbits.	None
	UF = N/A	Acute RfD = Not Applicable	

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR METHOXYFENOZIDE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Chronic Dietary (Non cancer) All Population Subgroups	NOAEL = 10.2 mg/kg/day	Hematological changes (decreased RBC, hemoglobin and/or hematocrit), liver toxicity (increased weights, hypertrophy), histopathological changes in thyroid (increased follicular cell hypertrophy, altered colloid), possible adrenal toxicity (increased weights).	2–Year combined chronic feeding/carcinogenicity, rats
	UF = 100; FQPA = 1X	Chronic RfD = 0.10 mg/kg/day Chronic Population Adjusted Dose (cPAD) = 0.10 mg/kg/day This cPAD applies to All population subgroups.	
Short-Term, Intermediate-Term, and Long-Term (Dermal)	None	No systemic toxicity was seen at the limit dose following repeated dermal application to rats.	None
Short-Term-Intermediate-Term, and Long-Term (Inhalation)	None	Based on low vapor pressure, the low acute toxicity of both the technical and formulated products as well as the application rate and application method, there is minimal concern for inhalation exposure.	None
Cancer	None	None.	None

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.544) for the residues of methoxyfenozide, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from methoxyfenozide in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on methoxyfenozide. Thus, the risk from acute exposure is considered negligible.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

a. A tier 1(assumptions: tolerance level residues and 100 percent crop treated) was conducted.

b. The established tolerances of 40 CFR 180.544 and the new tolerances established today were included in the analysis.

c. Anticipated residues and percent crop treated were not used in this analysis.

d. The processing factors applied were the DEEM default values.

As shown in table 2 of this preamble, the resulting dietary food exposures occupy up to 34.3% of the Chronic PAD for the most highly exposed population subgroup, children, 1–6 years old. These results should be viewed as conservative (health protective) risk estimates. Refinements such as use of percent crop-treated information and/or anticipated residue values would yield even lower estimates of chronic dietary exposure.

TABLE 2.—SUMMARY:CHRONIC DIETARY EXPOSURE ANALYSIS BY DEEM (TIER 1)

Population Subgroup[1]	Exposure (mg/kg/day)	% of Chronic PAD[2]
U.S. Population (Total)	0.018704	18.7
All infants (<1 year old)	0.020335	20.3
Nursing infants	0.010197	10.2
Non-nursing infants	0.024603	24.6

TABLE 2.—SUMMARY:CHRONIC DIETARY EXPOSURE ANALYSIS BY DEEM (TIER 1)—Continued

Population Subgroup[1]	Exposure (mg/kg/day)	% of Chronic PAD[2]
Children (1–6 years old)	0.034286	34.3
Children (7–12 years old)	0.024543	24.5
Females 13+ (nursing)	0.021335	21.3
Non-hispanic/non-white/non-black	0.021910	21.9

[1] The subgroups listed are: (1) the U.S. Population (total); (2) those for infants and children; (3) the most highly exposed of the females subgroups, in this case Females 13+ (nursing), and (4) the most highly exposed of the remaining subgroups, in this case Non-hispanic/non-white/non-black.
[2] Percent Chronic PAD = (Exposure ÷ Chronic PAD) x 100.

iii. *Cancer*. Methoxyfenozide is classified as a ''not likely'' human carcinogen. Therefore this risk is considered negligible.

iv. *Anticipated residue and percent crop treated information*. Anticipated residue and percent crop treated information was not used in the Agency's assessment.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for methoxyfenozide in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of methoxyfenozide.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to methoxyfenozide they are further discussed in the aggregate risk sections.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of methoxyfenozide for acute exposures are estimated to be 290 parts per billion (ppb) for surface water and 12 ppb for ground water. The EECs for chronic exposures are estimated to be 197 ppb for surface water and 12 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Methoxyfenozide is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether methoxyfenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that methoxyfenozide has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The toxicology database for methoxyfenozide included acceptable developmental toxicity studies in both

rats and rabbits as well as a 2–generation reproductive toxicity study in rats. The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methoxyfenozide.

3. *Conclusion*. The 10X safety factor for the protection of infants and children (as required by FQPA) has been removed (i.e. reduced to 1x) for the following reasons:

- The toxicology data base for methoxyfenozide is complete for assessment of potential hazard to infants and children.
- Based on weight-of-the-evidence considerations, the HIARC determined that a developmental neurotoxicity study in rats is not required to support the registration of methoxyfenozide.
- In developmental toxicity studies in rats and rabbits (MRID 44638201, 44617726), no increased susceptibility in fetuses as compared to maternal animals was observed following *in utero* exposures.
- In a 2-generation reproduction study in rats (MRID 44617727), no increased susceptibility in pups as compared to adults was observed following *in utero* and post-natal exposures.
- The exposure assessments will not underestimate the potential dietary (food and drinking water) or non-dietary exposures for infants and children from the use of methoxyfenozide.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD -(average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. No appropriate toxicological endpoint attributable to a single (acute) dietary exposure was identified. No acute risk is expected from exposure to methoxyfenozide.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to methoxyfenozide from food will utilize 18.7% of the cPAD for the U.S. population, 24.6% of the cPAD for non-nursing infants and 34.3% of the cPAD for children (1–6 years old). There are no residential uses for methoxyfenozide that result in chronic residential exposure to methoxyfenozide. In addition, there is potential for chronic dietary exposure to methoxyfenozide in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—DWLOCS FOR CHRONIC (NON-CANCER) DIETARY EXPOSURE

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)[1]	SCI-GROW (µg/L)	GENEEC 56–day avg (µg/L)	DWLOC (µg/L)[2,3,4]
U.S. Population (total)	0.10	0.019	0.081	12	197	2,800
Females 13+[5]	0.10	0.021	0.079	12	2,400	
Infants/Children[5]	0.10	0.034	0.066	12	197	660
Other[5]	0.10	0.022	0.078	12	197	2,700

[1] Maximum Water Exposure (mg/kg/day) = Chronic PAD (mg/kg/day) -[Chronic Food Exposure + Chronic Residential Exposure (mg/kg/day)]. Methoxyfenozide has no registered residential uses.

[2] DWLOC (µg/L) = [Maximum water Exposure (mg/kg/day) x body wt (kg)] ÷ [(10^{-3} mg/µg) x water consumed daily (L/day)]. µg/L = parts per billion.

[3] EPA default body weights are: General U.S. Population, 70 kg;Males (13+ years old), 70 kg;Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.

[4] EPA default daily drinking rates are 2 L/day for Adults and 1 L/day for Children.

[5] Within each of these subgroups, the subpopulation with the highest (chronic) food exposure was selected; namely, Females (13+/nursing); Children 1–6 yrs;and, Non-hispanic/non-white/non-black, respectively.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Methoxyfenozide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Methoxyfenozide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Methoxyfenozide is classified as a ''not likely'' human carcinogen. Therefore, exposure to methoxyfenozide is expected to create at most a negligible risk of cancer.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to methoxyfenozide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

1. *Enforcement methods for target crops.* Adequate enforcement methods are available for determination of methoxyfenozide residues in plant commodities. The similar methods that are used vary depending on the matrices involved. The enforcement method for cottonseed is TR 34–96–88 (high production liquid chromatography using ultraviolet detection (HPLC/UV); MRID 44617821), which has undergone a successful petition method validation (PMV) trial conducted by EPA (D261663). The enforcement method for pome fruit (also proposed for globe artichoke and lychee) is TR 34–98–87 (HPLC/UV; MRID 44626304), which has also undergone a successful PMV trial conducted by EPA (D261664). The other proposed enforcement methods are on: corn, TR 34–00–38 (HPLC/UV; MRID 45213504); tree nuts, TR 34–00–107 (HPLC/UV; MRID 45373503); stone fruit, TR 34–00–109 (HPLC/UV; MRID 45313302); leafy and Brassica (cole) vegetables, fruiting vegetables, grapes and raisins, TR 34–99–74 (HPLC/UV or MS; MRID 44873410). Adequate confirmatory method validation, radiovalidation, and independent laboratory validation (ILV) data for these methods have been provided.

2. *Enforcement method for rotational crops.* Method TR 34–00–41(MRID 45194701) is designated as the enforcement method for indirect or inadvertent residues in rotational crops (D269986). The method determines residues of methoxyfenozide (HPLC/UV) in high moisture crops; and residues of methoxyfenozide and its metabolites RH–117,236, RH–151,055, and RH–152,072 (HPLC/MS) in low moisture crops. Adequate confirmatory method validation, radiovalidation, and ILV data have been submitted. EPA concluded (D274209) a PMV trial on this method was not needed because of its similarity to TR 34–98–87.

3. *Enforcement methods for animal commodities.* The tolerance enforcement method for animal commodities (except poultry) is TR 34–98–106 (MRID 44626305), which has undergone a successful PMV trial conducted by EPA (D261665). The method determines residues of parent methoxyfenozide (HPLC/UV) in fat, cream, milk, and muscle;and residues of methoxyfenozide and its metabolite RH–141,518 (HPLC/MS) in liver and kidney (D249438). A similar method, TR 34–00–40 (MRID 45213505), will be the enforcement method for poultry commodities. TR 34–00–40 determines methoxyfenozide in fat (HPLC/UV) and muscle (HPLC/MS);and methoxyfenozide and RH–141,518 (HPLC/MS) in eggs and liver (D269969). EPA concluded (D274209) a PMV trial on this method was not needed because of its similarity to TR 34–98–106. Adequate confirmatory method validation, radiovalidation, and ILV data have been submitted for both methods.

4. *Multiresidue methods testing.* Methoxyfenozide is not recoverable by the Food and Drug Administration multiresidue method protocols of the Pesticide Analytical Method, Volume I (D249438). Test data for metabolites RH–141,518, RH–117,236, RH–151,055, and RH–152,072 are also required, but have not been submitted. Submission of such test data will be made a condition of registration.

These methods may be requested from: Calvin Furlow, PIRIB, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: *furlow.calvin@epa.gov*.

B. International Residue Limits

There are no Codex or Canadian MRLs established for residues of methoxyfenozide. Mexican MRLs are established for residues of methoxyfenozide in cottonseed (0.05 ppm) and maize (0.01 ppm). The U.S. tolerances on these commodities are 2.0 ppm and 0.05 ppm, respectively. Based on the current use patterns, the U.S. tolerance levels can not be reduced to harmonize with the Mexican MRLs, so incompatibility will exist.

C. Conditions

Submission of test data showing the recovery of metabolites RH–141,518, RH–117,236, RH–151,055, and RH–152,072 through the multiresidue test protocols of PAM, Vol. 1.

Submission of additional field accumulation trials (the 24 reportedly in progress). In the interim period, only time-limited tolerances (5 year) should be established.

- Submission of the following additional field trials, conducted per their respective proposed use pattern:
- Three for spinach (one each from Regions 1, 2, and 10)
- Two for celery (both from Region 3, preferably using Intrepid 2F)
- Three for mustard greens (one each from Regions 2, 3, and 10)
- Two for plums (one each from Regions 10 and 11)

Submission of the following additional information from the hen feeding study:

- Results of analysis (to be conducted) of the fat and meat (muscle) samples for residues of RH–141,518;
- Freezer storage stability data that covers the period of time these poultry fat and meat (muscle) samples have been maintained in storage;and,
- Revised tolerances and tolerance expression (to include RH 141,518) for these matrices, if warranted.

V. Conclusion

Therefore, tolerances are established for residues of the insecticide methoxyfenozide in or on almond, hulls; artichoke, globe; cattle, fat; corn, field, grain; corn, field, forage; corn, field, stover; corn, oil; corn, aspirated grain fractions; corn, sweet (K + CWHR); corn, sweet, forage; corn, sweet, stover; fruit, stone, group (except plum, fresh prune); goat, fat; grape; horse, fat; lime, Spanish; longan; lychee; milk; nut, tree, group; pistachio; plum (fresh prune); poultry, fat; poultry, meat; pulasan; raisin; rambutan; sheep, fat; vegetable, fruiting (except cucurbits), group; vegetable, leafy (except Brassica), leafy greens subgroup; vegetable, leafy (except Brassica), leaf petioles subgroup; vegetable, leafy, Brassica (cole), head and stem subgroup; vegetable, leafy, Brassica (cole), greens subgroup at 25.0, 3.0, 0.50,0.05, 15.0, 125.0, 0.20, 2.0, 0.05, 30.0, 60.0, 3.0, 0.50, 1.0,0.50, 2.0,2.0, 2.0 0.10, 0.10,0.10,0.30, 0.02, 0.02, 2.0, 1.5, 2.0, 0.5, 2.0, 30.0, 25.0, 7.0 and 30.0 part per million (ppm) respectively and for the combined residues of methoxyfenozide and its glucuronide metabolite in or on cattle,

liver; cattle, meat byproducts (except liver); eggs; goat, liver; goat meat byproducts (except liver); horse, liver; horse, meat byproducts (except liver); poultry, liver; poultry, meat byproducts (except liver); sheep, liver; and sheep, meat byproducts (except liver) at 0.40, 0.10, 0.02, 0.40, 0.10, 0.40, 0.10, 0.10, 0.02, 0.40 and 0.10 part per million (ppm) respectively. These petitions also requested that 40 CFR 180.544 be amended by establishing time limited tolerances for the indirect or inadvertent residues for methoxyfenozide in or on vegetable, bulb, group; vegetable, root and tuber, group; and vegetable, root and tuber, leaves, group when present therein as a result of the application of methoxyfenozide to growing crops at 0.20, 0.10 and 0.20 part per million (ppm) respectively and time limited indirect or inadvertent combined residues for methoxyfenozide and its metabolites RH–117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid *N*-tert-butyl-*N*'-(3-hydroxy-2-methylbenzoyl) hydrazide, RH–151,055 glucose conjugate of RH–117,236; 3,5-dimethylbenzoicacid *N*-tert-butyl-*N*-[3(β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide and RH–152,072 the malonylglycosyl conjugate of RH 117,236 in or on animal feed, non-grass (forage, fodder, straw, hay), group; grain, cereal, forage, fodder, and straw, group; grass, forage, fodder, and hay, group; herbs and spices, group; vegetable, legume, group; and vegetable, legume, foliage, group when present therein as a result of the application of methoxyfenozide to growing crops at 10.0, 10.0, 10.0, 10.0, 0.10 and 10.0 part per million (ppm) respectively.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0219 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 19, 2002.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0219, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact;there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary;and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the

Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks*(62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 16, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.544 is revised to read as follows:

§ 180.544 Methoxyfenozide;tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide methoxyfenozide per se; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide in or on the following food commodities:

Commodity	Parts per million
Almond, hulls	25
Apple, wet pomace	7.0
Artichoke, globe	3.0
Brassica, head and stem, subgroup	7.0
Brassica, leafy greens, subgroup	30
Cattle, fat	0.50
Cattle, meat	0.02
Corn, field, forage	15
Corn, field, grain	0.05
Corn, field, refined oil	0.20
Corn, field, stover	125
Corn, sweet, forage	30
Corn, sweet, kernal plus cob with husks removed	0.05
Corn, sweet, stover	60
Cotton, gin byproducts	35
Cotton, undelinted seed	2.0
Fruit, pome, group	1.5
Fruit, stone, group, except fresh prune plum	3.0
Goat, fat	0.50
Goat, meat	0.02
Grain, aspirated fractions	2.0
Grape	1.0
Grape, raisin	1.5
Hog, fat	0.1
Hog, meat	0.02
Horse, fat	0.50
Horse, meat	0.02
Leaf petioles subgroup	25
Leafy greens subgroup	30
Longan	2.0
Lychee	2.0
Milk	0.10
Nut, tree, group	0.10
Pistachio	0.10
Plum, prune, fresh	0.30
Poultry, fat	0.02
Poultry, meat	0.02

Commodity	Parts per million
Pulasan	2.0
Rambutan	2.0
Sheep, fat	0.50
Sheep, meat	0.02
Spanish lime	2.0
Vegetable, fruiting, group	2.0

(2) For combined residues of the insecticide methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide and its glucuronide metabolite RH-141,518; β-D-Glucopyranuronic acid, 3-[2-(1,1-dimethylethyl)-2-(3,5-dimethylbenzoyl)-hydrazino]carbonyl-2-methylphenyl-] in the following commodities:

Commodity	Parts per million
Cattle, liver	0.40
Cattle, meat byproducts, except liver	0.10
Egg	0.02
Goat, liver	0.40
Goat, meat byproducts, except liver	0.10
Hog, liver	0.1
Hog, meat byproducts, except liver	0.02
Horse, liver	0.40
Horse, meat byproducts, except liver	0.10
Poultry, liver	0.10
Poultry, meat byproducts, except liver	0.02
Sheep, liver	0.40
Sheep, meat byproducts, except liver	0.10

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the insecticide methoxyfenozide in connection with the use of the pesticide under section 18 emergency exemption granted by EPA. The tolerances will expire on the dates specified in the following tables.

Commodity	Parts per million	Expiration/revocation date
Corn, field, forage	10	12/31/03
Corn, field, grain	0.02	12/31/03
Corn, field, stover	75	12/31/03
Corn, oil	0.1	12/31/03
Soybean, aspirated grain fractions	20	12/31/03
Soybean, forage	10	12/31/03
Soybean, hay	75	12/31/03
Soybean, refined oil	1.0	12/31/03
Soybean, seed	0.04	12/31/03

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* (1) Tolerances are established for the indirect or inadvertent residues of the insecticide methoxyfenozide per se; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide in or on the following raw agricultural commodities, when present therein as a result of the application of methoxyfenozide to growing crops as listed in paragraph (a) of this section:

Commodity	Parts per million	Expiration/Revocation Date
Vegetable, bulb, group	0.20	09/30/07
Vegetable, root and tuber, group	0.10	09/30/07
Vegetable, leaves of root and tuber, group	0.20	09/30/07

(2)Tolerances are established for the indirect or inadvertent combined residues of methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide and its metabolites RH-117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid *N*-tert-butyl-*N*'-(3-hydroxy-2-methylbenzoyl) hydrazide, RH-151,055 glucose conjugate of RH-117,236; 3,5-dimethyl benzoic acid *N*-tert-butyl-*N*-[3 (β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide and RH-152,072 the malonylglycosyl conjugate of RH 117,236 in or on the following raw agricultural commodities, when present therein as a result of the application of methoxyfenozide to growing crops as listed in paragraph (a) of this section:

Commodity	Parts per million	Expiration/Revocation Date
Animal feed, non-grass, group	10.0	09/30/07
Grain, cereal, forage, fodder and straw, group	10.0	09/30/07
Grass, forage, fodder, and hay, group	10.0	09/30/07
Herb and spice, group	10.0	09/30/07
Vegetable, legume, group	0.10	09/30/07
Vegetable, foliage of legume, group	10.0	09/30/07

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket Nos. 96–115, 96–149; FCC 02–214]

Implementation of the Telecommunications Act of 1996: Telecommunications Carriers' Use of Customer Proprietary Network Information and Other Customer Information; Implementation of the Non-Accounting Safeguards of Sections 271 and 272 of the Connumications Act of 1934, as Amended

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document adopts rules to implement section 222 of the Communications Act of 1934 (as amended by the Telecommunications Act of 1996), which governs carriers' use and disclosure of customer proprietary network information (CPNI). This document affirms the continued use of the total service approach to define what carriers may do under section 222(c)(1) without notice to customers, and allows a carrier to choose whether to use an opt-out or opt-in approval method for obtaining customer approval for a carrier to use its customer's individually identifiable CPNI for the purpose of marketing communications-related services to that customer. Specifically, this document allows the use of CPNI by carriers or disclosure to their affiliated entities providing communications-related services, as well as third-party agents and joint venture partners providing communications-related services, only after a carrier receives a customer's knowing consent in the form of notice and ''opt-out'' approval. This document also permits disclosure of CPNI to unrelated third parties or to carrier affiliates that do not provide communications-related services requires express customer consent, described as ''opt-in'' approval. This document also further refines the rules governing the process by which carriers provide notification to customers of their CPNI rights. Specifically, it clarifies the form, content and frequency of carrier notices. Additionally, this document affirms the Federal Communications Commission's conclusion that customers' preferred carrier (PC) freeze information constitutes CPNI and thereby warrants privacy protection pursuant to section 222, and announces the Commission's decision to forbear from imposing the express consent requirements announced in this document with respect to PC-freezes. This document also reaffirms existing Commission rules addressing winback and retention marketing, and declines to adopt further rules regarding a carrier's denial of CPNI to another carrier with customer authorization.

DATES: Effective October 21, 2002, except §§ 64.2007, 64.2008, and 64.2009, which contain information collection requirements that are not effective until approved by the Office of Management and Budget. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date of these rules.

FOR FURTHER INFORMATION CONTACT: Marcy Greene, Attorney-Advisor, Competition Policy Division, Wireline Competition Bureau, at (202) 418–2410, or via the Internet at *mgreene@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Third Report and Order in CC Docket Nos. 96–115 and 96–149, adopted July 16, 2002, and released July 25, 2002. The complete text of this Report and Order is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC, 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail at *qualexint@aol.com*. It is also available on the Commission's Web site at *http://www.fcc.gov*.

Synopsis of the Report and Order

1. The Commission resolves in this Order several issues in connection with carriers' use of customer proprietary network information (''CPNI'') pursuant to section 222 of the Telecommunications Act of 1996. Through section 222, Congress recognized both that telecommunications carriers are in a unique position to collect sensitive personal information and that customers maintain an important privacy interest in protecting this information from disclosure and dissemination. The rules adopted by the Commission focus on the nature of the customer approval needed before a carrier can use, disclose or permit access to CPNI.

2. *Background.* This proceeding was initiated in 1996 to implement section 222 of the Communications Act of 1934 (as amended), which governs carriers' use and disclosure of CPNI. On February 26, 1998, the Commission adopted regulations implementing section 222 in its *CPNI Order*. [63 FR 20236, April 24, 1998]. In particular, it concluded that section 222(c)(1) of the Act allows a carrier to use a customer's CPNI, derived from the complete service subscribed to from that carrier, for marketing purposes within the existing service relationship. This is known as the ''total service approach.'' The Commission also concluded that carriers must notify the customer of the customer's rights under section 222 and then obtain express written, oral or electronic customer approval—a ''notice and opt-in'' approach—before a carrier may use CPNI to market services outside the customer's existing service relationship with that carrier. On September 3, 1999, the Commission released an *Order on Reconsideration* [64 FR 53242, Oct. 1, 1999] that affirmed the opt-in approach, but streamlined the CPNI rules so that carriers could use CPNI to market customer premises equipment and information services without customer approval, and lessened carriers' CPNI record-keeping responsibilities. It also eliminated restrictions on a carrier's ability to use CPNI to regain customers that switched to another carrier, known as ''winbacks.''

3. After the Commission adopted the *Order on Reconsideration*, but prior to its release, the Court of Appeals for the Tenth Circuit vacated portions of the 1998 *CPNI Order*. The court found that the Commission did not show that the opt-in form of consent protected privacy and promoted competition in a manner consistent with the First Amendment of the U.S. Constitution.

4. In an October 6, 2000 Order, *AT&T* v. *Bell Atlantic* (denying a complaint by AT&T regarding the manner in which Bell Atlantic markets the services of its long distance affiliate to its local exchange customers), the Commission interpreted the Tenth Circuit's vacatur as applying only to the discrete issue that was before the court. On September 7, 2001, the Commission released a *Clarification Order and Second Further Notice of Proposed Rulemaking* [66 FR 50140, Oct. 2, 2001] that determined that all CPNI rules except those relating to opt-in remained in effect, and that carriers may choose to obtain customer approval by means of an opt-out approach until the Commission adopted